510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The Assigned 510(k) number is k131236

Submitter: UCP Biosciences, Inc

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San Jose, CA 95014

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NOV 07 2013

Date: November 1, 2013

Contact Person: Dr. Nancy Chen

Trade Name: UCP Home Pregnancy Midstream Test

UCP Home Pregnancy Dip Card/Strip

UCP Home Pregnancy Cassette Test

UCP Pregnancy Dip Card/Strip

UCP Pregnancy Cassette Test

Common Name: Pregnancy Test

Product Code: LCX, JHI

Regulation Section: 21 CFR §862.1155

Panel: Clinical Chemistry (75)

Device Classification: II

Predicate Device: The Quik-Check Home Pregnancy Test Device (k012215)

Product Description:

UCP Home Pregnancy Test and UCP Pregnancy Test is a rapid chromatographic immunoassay for qualitatively detection of the elevated hCG in urine. The tests can be performed without the use of an instrument.

Intended Use:

See Indications For Use.

Indication For Use

- UCP Home Pregnancy Cassette Test is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

- UCP Home Pregnancy Dip Card/Strip is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

- UCP Home Pregnancy Midstream Test is rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Over the Counter Use Only.

- UCP Pregnancy Cassette Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

- UCP Pregnancy Dip Card/Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

Comparison to Predicate Devices:

A summary comparison of the features of the UCP Home Pregnancy Test, UCP Pregnancy Test and ACON's The Quik-Check Home Pregnancy Test Device is provided in Table 1 as the following:

Table 1

Parameter	**UCP Home Pregnancy Test, UCP Pregnancy Test** (Candidate Device)	**The Quik-Check Home Pregnancy Test Device** (Predicate Device)
Intended Use	Qualitative detection of hCG in human urine to aid in early detection of pregnancy	Qualitative detection of hCG in human urine to aid in early detection of pregnancy
Format	Midstream, Dip Card/Strip, Cassette	Strip, Cassette
Test Principle	Chromatographic immunoassay, Lateral flow	Chromatographic immunoassay, Lateral flow
Test Time	3 minutes	3 minutes
Sensitivity	25 mIU/mL	25 mIU/mL
Specificity	No interferences when tested with LH, FSH and TSH	No interferences when tested with LH, FSH and TSH
Standardization	WHO Fourth International Standard	WHO Third International Standard

Safety and Effectiveness Data:

Comparison/Consumer Studies:

Comparison studies between UCP Home Pregnancy Tests/UCP Pregnancy Tests and a predicate device were conducted by the lab professionals, using 100 urine specimens collected from 100 women who fit into the following categories: childbearing age, suspected pregnant women, women early in pregnancy, and the first trimester of pregnancy. Each urine specimen was tested by the lab professionals, who performed testing by using UCP Home Pregnancy Tests/UCP Pregnancy Tests and a predicate device. In addition, 100 lay users also tested the urine specimens by using UCP Home Pregnancy Tests. There was 100% agreement between UCP Home Pregnancy Test results by lay users and by the professionals. The results were also 100% in agreement between UCP Home Pregnancy Tests/UCP Pregnancy Tests and the predicate device results tested by the professionals. The lay users were asked the questions including whether the test was easy to run, the results were easy to read, the test results were easy to read. Participant responses support that the lay users can understand how to run the test, interpret the test results by properly following the test instruction.

Other Information about Performance Characteristics:

The performance characteristics of UCP Home Pregnancy Tests/UCP Pregnancy Tests including the precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study have been also established. The results have demonstrated that UCP Home Pregnancy Tests/UCP Pregnancy Tests performs satisfactorily when used according to the package inserts.

Conclusion:

The performance data in this submission supports UCP Home Pregnancy Midstream Test, UCP Home Pregnancy Dip Card/Strip, UCP Home Pregnancy Cassette Test, UCP Pregnancy Dip Card/Strip, and UCP Pregnancy Cassette Test is substantially equivalent to the predicate device The Quik-Check Home Pregnancy Test (k012215)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 7, 2013

UCP Biosciences, Inc.
C/O Nancy Chen
1445 Koll Circle, Suite 111
SAN JOSE CA 95112

Re: K131236
Trade/Device Name: UCP Pregnancy Cassette Test
UCP Pregnancy Dip/Card Strip
UCP Home Pregnancy Cassette Test
UCP Home Pregnancy Midstream Test
UCP Home Pregnancy Dip/Card Strip
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (hCG) test system
Regulatory Class: II
Product Code: LCX, JHI
Dated: August 12, 2013
Received: August 15, 2013

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131236

Device Name: UCP Pregnancy Cassette Test
UCP Pregnancy Dip Card/Strip
UCP Home Pregnancy Cassette Test
UCP Home Pregnancy Midstream Test
UCP Home Pregnancy Dip Card/Strip

Indications for Use:

UCP Pregnancy Cassette Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

UCP Pregnancy Dip Card/Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The device is intended for Prescription Use Only including at point of care sites.

Prescription Use __X__ And/Or Over the Counter Use ___

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

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UCP Pregnancy Dip Card/Strip
UCP Home Pregnancy Cassette Test
UCP Home Pregnancy Midstream Test
UCP Home Pregnancy Dip Card/Strip

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UCP Home Pregnancy Dip Card/Strip is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

Prescription Use ___ And/Or Over the Counter Use _X_

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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